



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 00-1282)

the Application of:

Jourdier et al.

Serial No.: 09/720,513

Filing Date: March 26, 2001

For: Mucosal Targeting Immunisation

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) Examiner: Bao Q. Li
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) Group Art Unit: 1648
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) Confirmation No.: 3546
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RESPONSE TO THE FINAL OFFICE ACTION MAILED SEPTEMBER 22, 2004

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

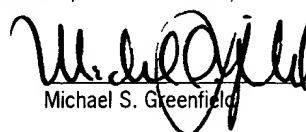
Please consider the following remarks made in response to the final Office Action mailed September 22, 2004.

Remarks begin on page 2 of this paper.

CERTIFICATE OF MAILING (37 C.F.R. 1.10)

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail envelope EV 334696495 US addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, February 22, 2005.

Date: February 22, 2005


Michael S. Greenfield

REMARKS

The claims remain rejected under 35 U.S.C. § 103(a) as obvious over Carrano *et al.*, Groswasser *et al.*, Stites *et al.*, and Bouvet *et al.* For the following reasons, the applicants respectfully traverse.

In maintaining the rejection and responding to the applicants' argument that the data on page 19 (which demonstrated an immune response in the iliac and inguinal lymph nodes that was 18 to 350 times that observed in the submaxillary and axillary lymph nodes and in the blood following administration to the thigh as claimed), the Examiner asserted that it would be expected that a better immune response would be observed nearer the site of injection. In response, the applicants now present another declaration of Therese-Marie Jourdier that presents experiments and data demonstrating that a greater immune response is observed in vaginal and rectal secretions of subjects when antigen administration is to the thigh (according to the invention) compared to when antigen administration is directly through vaginal and rectal routes.

As explained in Dr. Jourdier's Declaration, five groups of four monkeys each were tested. One group (Group 1) was administered adjuvanted antigen by the vaginal and rectal routes. Two groups were administered adjuvanted antigen to the rectus femoris (Group 2) or the gracilis (Group 4). Groups 3 and 5 were administered adjuvanted antigen to the thigh as for Group 2 and Group 4, respectively, followed by administration via the vaginal and rectal routes. Vaginal and rectal secretions and blood were collected and, after the last immunization, lymph nodes were analyzed.

The data show that no specific IgG or IgA response was found in the vaginal or rectal secretions of monkeys administered antigen directly via the vaginal and rectal routes (Group 1). Both specific IgA and IgG responses were detected, however, in the vaginal and rectal secretions of monkeys administered antigen to the thigh (Groups 2-5). No boost in specific IgG or IgA response was observed in monkeys administered antigen via the vaginal and rectal routes after administration to the thigh (Groups 3 and 5).

Consistent with the Examiner's assertion that one would expect a greater immune response nearer the site of administration, Dr. Jourdier attests that one would expect to improve the immune response at the targeted mucosal sites by administration directly to that site. Unexpectedly, the data are to the contrary – a greater immune response was observed in the vaginal and rectal secretions

when administration was to a distal site (the thigh) compared to local administration (vaginally and rectally). Dr. Jourdier further attests that she is unaware of any basis by which one of ordinary skill art could have expected that administration to the thigh would result in a specific targeted response in a distal area, generally, and in the rectogenitourinary lymph node system and mucous membranes, in particular.

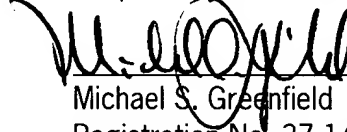
Significantly, none of the art cited by the Examiner as the basis for this obviousness rejection teaches or suggests the properties observed with the presently claimed method. Accordingly, the claims cannot be obvious over the cited art.

In view of the foregoing, and for the reasons previously proffered, the applicants respectfully request reconsideration and withdrawal of the pending § 103 rejection.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Date: February 22, 2005

Respectfully submitted,



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